Bisphenol A Alternatives in Thermal Paper

Chapter 1

Introduction

FINAL REPORT

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List of Acronyms and Abbreviations

AIM	Analog Identification Methodology
ACR	Acute to Chronic Ratio
ADME	Absorption, Distribution, Metabolism, and Excretion
AIST	Advanced Industrial Science and Technology
ASTM	American Society for Testing and Materials
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMD	Benchmark Dose
BMDL	Benchmark Dose Lower-confidence Limit
BPA	Bisphenol A
BPS	Bisphenol S
BOD	Biochemical Oxygen Demand
CASRN	Chemical Abstracts Service Registry Number
CDC	Centers for Disease Control and Prevention
CHO	Chinese Hamster Ovary Cells
ChV	Chronic Value
CPSC	Consumer Product Safety Commission
CVL	Crystal Violet Lactone
DfE	Design for the Environment
DOC	Dissolved Organic Carbon
dpi	Dots per inch
EC_{50}	Half Maximal Effective Concentration
ECHA	European Chemicals Agency
ECOSAR	Ecological Structure Activity Relationships
EDSP	Endocrine Disruptor Screening Program
EEC	European Economic Community
Eh	Redox potential
EKG	Electrocardiogram
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
EPI	Estimations Program Interface
ERMA	Environmental Risk Management Authority
EU	European Union
EWG	Environmental Working Group
FDA	U.S. Food and Drug Administration
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
GLP	Good Laboratory Practice
HGPRT	Hypoxanthine-Guanine Phosphoribosyl-Transferase
HIPAA	Health Insurance Portability and Accountability Act of 1996
HPLC	High Performance Liquid Chromatography
HPV	High Production Volume
HSDB	Hazardous Substances Data Bank
IARC	International Agency for Research on Cancer
IR	Infrared

IRIS	Integrated Risk Information System
IUCLID	International Uniform Chemical Information Database
K_{oc}	Soil adsorption coefficient
K_{ow}	Octanol/water partition coefficient
LC_{50}	Median Lethal Concentration
LCA	Life-cycle Assessment
LD_{50}	Median Lethal Dose
LD	Lactation Day
LFL	Lower Limit of Flammability
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effective Concentration
MDI	Mean Daily Intake
MF	Molecular Formula
MITI	Japanese Ministry of International Trade and Industry
MW	Molecular Weight
MSDS	Material Safety Data Sheet
NAICS	North American Industry Classification System
NES	No Effects at Saturation
NGO	Non-Governmental Organization
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIOSH	National Institute for Occupational Safety and Health
NIR	Near Infrared
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
NTP	National Toxicology Program
OECD	Organisation for Economic Cooperation and Development
OPPT	Office of Pollution Prevention and Toxics
P2	Pollution Prevention
PBB	Poly-Brominated Biphenyls
PBDE	Polybrominated Diphenyl Ether
PBT Profiler	Persistent, Bioaccumulative, and Toxic (PBT) Chemical Profiler
PMN	Premanufacture Notice
PNEC	Predicted No Effect Concentration
POS	Point-of-sale
ppb	parts per billion
ppm	parts per million
PVC	Polyvinyl Chloride
REACH	**R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emical substances
RoHS	Restriction of Hazardous Substances
SAR	Structure Activity Relationship
SCAS	Semi-Continuous Activated Sludge
SF	Sustainable Futures
SMILES	Simplified Molecular-Input Line-Entry System
SPARC	Sparc Performs Automated Reasoning in Chemistry

TDI	Total Daily Intake
TOC	Total Organic Carbon
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
QSAR	Quantitative Structure Activity Relationships
UFL	Upper Limit of Flammability
USGS	U.S. Geological Survey
WHO	World Health Organization
WWTP	Wastewater Treatment Plant

1. Introduction

As part of its effort to enhance the Agency's current chemicals management program, the U.S. Environmental Protection Agency (EPA) has taken steps to identify chemicals that may pose environmental and health concerns. In 2009-2011, EPA developed action plans to investigate potential regulatory and voluntary actions. In March 2010, EPA released a chemical action plan that summarizes hazard, exposure, and use information on bisphenol A (BPA) and identifies actions EPA is considering.[1] Under this action plan, EPA's Design for the Environment (DfE) Branch initiated this alternatives assessment: *BPA Alternatives in Thermal Paper.* Thermal paper was selected for evaluation based on concern for potential exposures to consumers and workers, releases to the environment, and stakeholder interest. DfE's Alternatives Assessment Program helps industries choose safer chemicals and provides a basis for informed decision-making by developing a screening-level comparison of potential human health and environmental impacts of chemical alternatives. Representatives from industry, academia, government, and non-governmental organizations (NGOs) provided input which DfE considered to select and evaluate alternatives to BPA in thermal paper[2] and develop this report. Although the purpose of DfE Alternatives Assessments is to provide information that will enable selection of safer alternatives, in some projects, clearly safer alternatives are not available. Hazard trade-offs complicate the interpretation of results. Nonetheless, the report contains helpful risk management information for thermal paper companies who are considering alternative chemicals.

BPA is a high production volume (HPV) chemical with U.S. production volume estimated at 2.4 billion pounds in 2007, with an estimated value of almost $2 billion (U.S. EPA 2010). It is a monomer used in manufacturing most polycarbonate plastics, the majority of epoxy resins, and other chemical products such as flame retardants. Recently, there has been heightened public attention around exposures to BPA and its potential effects as an environmental pollutant. Because BPA is a reproductive, developmental, and systemic toxicant in animal studies and interacts with estrogen receptors, there are questions about its potential impact, particularly on children's health and ecosystems. Several government entities have published reports examining potential human health and environmental hazards associated with BPA exposure. Such entities include a number of regulatory agencies in the European Union (EU), Health Canada and Environment Canada, Japan's National Institute of Advanced Industrial Science and Technology (AIST), the U.S. Food and Drug Administration (FDA), and the U.S. National Institute of Environmental Health Sciences National Toxicology Program (NTP). Additional research is underway, particularly concerning whether BPA may cause effects at low doses (U.S. EPA 2010).

Approximately 94% of BPA is used as a monomer to make polycarbonate plastic and epoxy resins (U.S. EPA 2010). Although most human exposure to BPA is believed to come from food and beverage packaging made from these materials, less than 5% of the BPA produced is used in food contact applications (U.S. EPA 2010). Apart from food-related uses, BPA-based materials are used in automotive and other transportation equipment, optical media such as DVDs,

[1] The BPA action plan is available online at http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/bpa_action_plan.pdf.
[2] The term "thermal paper" used in this report refers to paper used in direct thermal transfer machines.

electrical/electronics equipment, construction, linings inside drinking water pipes, thermal paper coatings, foundry casting, and elsewhere.

BPA is a commonly used developer in a number of thermal paper applications, such as point-of-sale (POS) receipts, but may also be used in other thermal paper applications such as airline tickets, event and cinema tickets, and labels. When used in thermal paper, BPA is present as "free" (i.e., discrete, non-polymerized) BPA, which is likely to be more available for exposure than BPA polymerized into a resin or plastic (U.S. EPA 2010). Upon handling, BPA in thermal paper can be transferred to skin, and there is some concern that residues on hands could be ingested through incidental hand-to-mouth contact (Zalko, Jacques et al. 2011). Furthermore, some studies suggest that dermal absorption may contribute some small fraction to the overall human exposure (Biedermann, Tschudin et al. 2010; Zalko, Jacques et al. 2011). European data indicate that the use of BPA in paper may also contribute to the presence of BPA in the stream of recycled paper and in landfills (JRC-IHCP 2010). Although there are currently no estimates for the amount of BPA used in thermal paper in the United States, in Western Europe, the volume of BPA reported to be used in thermal paper in 2005/2006 was 1,890 tonnes per year, while total production was estimated at 1,150,000 tonnes per year (JRC-IHCP 2010), which accounts for roughly 0.2% of the annual use of BPA.

As described in the action plan, EPA's DfE Branch initiated this multi-stakeholder effort alternatives assessment: *BPA Alternatives in Thermal Paper*.[3] DfE's Alternatives Assessment Program provides a basis for informed decision-making by developing a screening-level comparison of potential human health and environmental impacts of chemical alternatives. The BPA Alternatives in Thermal Paper Partnership was formed in July 2010 and includes a diverse array of stakeholders, such as thermal paper manufacturers, thermal paper converters, chemical manufacturers, POS equipment manufacturers, retailers, trade associations, NGOs, green chemistry and technical experts, and international governmental organizations. Partners engaged with DfE to identify and evaluate potential alternatives to BPA in thermal paper and develop this report.

This alternatives assessment evaluated the alternatives that were judged by stakeholders as most likely to be functional in thermal printing applications. Selection of a chemical for evaluation in the report does not denote environmental preferability. Rather, the report provides information that will help decision-makers consider environmental and human health profiles for all evaluated chemicals, so that they can choose the safest possible functional alternative. This report also presents general information on exposures to thermal paper, life-cycle considerations, and some considerations for weighing human health and environmental information with other factors, such as cost and performance.

1.1 Purpose of the BPA in Thermal Paper Alternatives Assessment

The purpose of the BPA in Thermal Paper Alternatives Assessment is to inform substitution by evaluating the hazards associated with likely functional alternatives to BPA, and make this information available to decision-makers and the public. Information generated from this effort will contribute to more informed decisions concerning the selection and use of developers in thermal paper technologies and the disposal and recycling of thermal paper.

[3] For more information on the DfE Program's Alternatives Assessments, see www.epa.gov/dfe/alternative_assessments.html.

1.2 Scope of the BPA in Thermal Paper Alternatives Assessment

The BPA in Thermal Paper Alternatives Assessment is an evaluation of potential hazards associated with thermal paper developers that are likely to be functional alternatives to BPA. Thermal paper systems include a developer and other components such as dyes and sensitizers. EPA recognizes that a change in the developer may require additional adjustments to the system.

An assessment of process chemicals (i.e., those used in the manufacture of BPA) and other chemicals used in the manufacture of thermal paper is beyond the scope of this assessment. Similarly, assessments of technologies that could replace thermal paper applications altogether, such as alternative printing technologies or electronic receipts, are also outside the scope of this assessment. Selected alternative technologies are briefly discussed in Chapter 6.

This report summarizes the outcomes of the alternatives assessment, and aims to improve understanding of the potential environmental and human health hazards of BPA and alternative developers in thermal paper throughout their life-cycles. It is intended to provide information that will inform industry and other stakeholders on the selection of alternative developers for use in thermal paper. This report does not provide a ranking of alternatives or provide guidance on the appropriate use of BPA or other alternatives; rather the information provided in this alternatives assessment is meant to assist decision makers in better understanding BPA and its potential chemical alternatives in thermal paper.

This report is organized as follows:

- *Chapter 1 (Introduction)*: provides background on the BPA Alternatives in Thermal Paper Partnership, including the purpose and scope of the assessment.
- *Chapter 2 (Products and Materials: BPA in Thermal Paper*): provides information on BPA and its use in thermal paper as a developer.
- *Chapter 3 (Background on Thermal Printing Technology)*: describes the thermal paper printing system and how developers interact with other components in the system to create a printed product.
- *Chapter 4 (Hazard Evaluation of Bisphenol A (BPA) and Alternatives)*: provides the results of the hazard assessment of BPA and the 19 alternatives identified for inclusion. This chapter also discusses how the alternatives were identified.
- *Chapter 5 (General Exposure and Life-cycle Information)*: details the human health and environmental exposure pathways of developers from thermal paper and other life-cycle considerations.
- *Chapter 6 (Considerations for Selecting Thermal Paper Developers)*: describes considerations involved with selecting an alternative developer to BPA in thermal paper. This chapter also discusses green chemistry options and alternative technologies that could be used in place of thermal paper applications.

1.3 DfE Alternatives Assessment as a Risk Management Tool

Among other actions, the Agency included an alternatives assessment for BPA in thermal paper as a suitable risk management tool in the BPA action plan. The Agency chose this tool to inform the chemical substitution that may occur as an outcome of other activities described in the action plan. The intent was to compare the intrinsic properties of chemical alternatives that may be substituted for BPA in thermal paper, based on a consistent and comprehensive set of endpoints. DfE Alternatives Assessments provide an opportunity to learn more about chemicals used in specific applications. This approach often complements other EPA activities, such as research or regulatory programs.

Alternatives assessments may include a comparison of the chemical of interest with design or process changes, alternative materials, or chemical substitutes. DfE Alternatives Assessments focus on the hazard characteristics of chemical alternatives, providing information on the environmental and human health profiles of each chemical included. In addition, DfE Alternatives Assessments describe intrinsic properties that inform our understanding of the potential for exposure and hazard. These properties include concerns associated with chemical structure, absorption potential, persistence and bioaccumulation. Industry and other stakeholders can use this information, in combination with an analysis of cost, performance, and other factors, to choose alternatives. DfE Alternatives Assessments can also identify the characteristics of safer alternatives and guide innovation and product development, especially when clearly preferable alternatives are not available.

Under this approach the health and environmental profiles in the alternatives assessments become the key variable and source of distinguishing characteristics. The potential impact of exposure attributes, including significant differences in environmental fate and transport based on persistence, bioaccumulation, and physical properties, are discussed in Chapters 4 and 5.

Alternatives assessments, life-cycle assessments (LCAs), and risk assessments are all tools that can be used to improve the sustainability profiles of chemicals and products. These tools, which can be complementary, should be selected according to the risk management need and other regulatory and policy considerations. DfE Alternatives Assessments establish a foundation upon which other tools, such as risk assessments and LCAs, can build.

Risk assessment and alternatives assessment are both based on the premise that risk is a function of hazard and exposure. Risk assessment characterizes the nature and magnitude of hazard and exposure from chemical contaminants and other stressors. DfE's "functional use" approach to alternatives assessment orients chemical evaluations within a given product type and functionality. Under this approach, factors related to exposure scenarios, such as the amount used, physical form, and route of exposure, can be quite similar within a given functional use, allowing for a focus on hazard reduction. When less hazardous alternatives have different physical/chemical profiles or require different use levels, it may be appropriate to also conduct an exposure assessment.

The substitutes evaluated in some DfE alternatives assessments include chemical alternatives that are of low concern for human health and environmental health hazards, while in other alternatives assessments, the chemical alternatives exhibit significant hazard trade-offs. When trade-offs are a concern, other approaches may be needed. For example, it may be necessary to gather additional information on exposure scenarios and the potential for control or mitigation of risks, such as design changes, alternative materials, or, when necessary, exposure controls. The National Institute for Occupational Safety and Health (NIOSH) Hierarchy of Controls illustrates the order of preference of potential control solutions (NIOSH 2011).

DfE Alternatives Assessment Furthers the Goals of Green Chemistry

The DfE Alternatives Assessment approach is aligned with green chemistry principles.[4] The relationship to two of those principles is especially noteworthy:

- *Principle 4:* Designing safer chemicals -- "Design chemical products to affect their desired function while minimizing their toxicity," and
- *Principle 10:* Design for degradation -- "Design chemical products so they break down into innocuous products that do not persist in the environment."

DfE incorporates these two green chemistry principles in its criteria and applies them in its assessment of chemical hazard and fate in the environment. This approach can enable identification of safer substitutes that emphasize greener chemistry and point the way to innovation in safer chemical design, where hazard becomes a part of a performance evaluation.

[4] http://www.epa.gov/sciencematters/june2011/principles.htm

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